

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

STANLEY JACKSON and BARBARA JACKSON	:	Case No.: <u>2:09-cv-1052</u>
Plaintiffs,	:	Judge: _____
v.	:	
C.B. FLEET COMPANY, INC. d/b/a FLEET LABORATORIES 4615 Murray Place Lynchburg, VA 24502	:	COMPLAINT AND JURY DEMAND
and	:	
C.B. FLEET HOLDING COMPANY, INC. 4615 Murray Place Lynchburg, VA 24502	:	
Defendants.	:	

Plaintiffs, by and through undersigned counsel, and for their Verified Complaint and Jury Demand against Defendants, allege upon information and belief as follows:

PARTIES

1. Plaintiff Stanley Jackson and Plaintiff Barbara Jackson are married and at all relevant times have jointly resided in Cincinnati, Ohio located in Hamilton County.
2. Defendant C.B. Fleet Company, Inc. is a closely-held Virginia corporation with its principle place of business located at 4615 Murray Place; Lynchburg, Virginia 24502. Defendant C.B. Fleet Company, Inc. is a citizen of Virginia.

3. Defendant C.B. Fleet Holding Company, Inc. is a Virginia corporation with its principle place of business located at 4615 Murray Place; Lynchburg, Virginia 24502. Defendant C.B. Fleet Holding Company, Inc. is a citizen of Virginia.

4. At all times relevant hereto, Defendant C.B. Fleet Company, Inc. has been the ultimate parent corporation of Defendant C.B. Fleet Holding Company, Inc.

5. At all times relevant hereto, the Defendants have been in the business of manufacturing, designing, formulating, producing, constructing, creating, assembling, rebuilding, selling, distributing, supplying, marketing, and/or placing into the stream of commerce, either directly or indirectly through third parties or related entities, the over-the-counter oral sodium phosphate bowel cleanser, Phospho-soda.

JURISDICTION AND VENUE

6. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between the parties, and the amount in controversy exceeds \$75,000.00, exclusive of interest and costs.

7. The Court has personal jurisdiction over Defendants consistent with the United States Constitution and the Ohio Constitution pursuant to O.R.C. § 2307.382 because the Defendants conduct business in Ohio, contract to supply goods and services in Ohio, and caused tortious injury in Ohio by acts or omissions inside Ohio and/or outside Ohio and by virtue of Defendants' regularly conducted business in Ohio from which they derive substantial revenue.

8. Venue in this district is appropriate under 28 U.S.C. § 1391 because a substantial part of the events giving rise to this claim occurred in the district as Plaintiff

Stanley Jackson ingested Phospho-soda in this district, resides in this district, and suffered injury in this district.

GENERAL ALLEGATIONS

9. The Defendants manufactured and marketed Phospho-soda, a sodium phosphate oral solution made from monobasic sodium phosphate and dibasic sodium phosphate. Defendants promoted, distributed, and/or sold Phospho-soda as a "laxative, for the relief of occasional constipation" and "purgative, for use as part of a bowel cleansing regimen in preparation for surgery, x-ray, or endoscopic examination."

10. The Defendants actively promoted a dosing regimen that included two separate doses of 45 mL (90 mL total) of the product for individuals intending to use it for pre-colonoscopy/bowel cleansing purposes. Defendants promoted such dosing regimen to physicians and the general public as being safe and effective despite the fact that the Federal Food and Drug Administration ("FDA") continuously refused to approve such dosing regimen, and scientific studies and reports indicated that lower doses were effective.

11. On December 11, 2008, the FDA announced that it had become aware of reports of acute phosphate nephropathy, a type of acute kidney injury, associated with the use of oral sodium phosphate products used for bowel cleansing prior to colonoscopy, including Phospho-soda.

12. Acute phosphate nephropathy is characterized by deposits of calcium-phosphate crystals in the renal tubules that may result in renal function impairment. It is a term used to describe the medical condition nephrocalcinosis when it is precipitated

by the ingestion of an oral sodium phosphate solution such as Phospho-soda. Patients who suffer such renal function impairment may require long-term dialysis if their kidneys are damaged significantly.

13. Through the warning on December 11, 2008, the FDA announced that it was requiring the addition of a “Black Box” Warning on two prescription oral sodium phosphate products, Visicol and OsmoPrep to warn patients of the risks of acute phosphate nephropathy. The FDA also required that the manufacturers develop and implement a risk evaluation and mitigation strategy to ensure that the products’ benefits outweighed their risks of injury to users. Finally, it required the manufacturers to implement a post-market clinical trial designed to evaluate the risk of renal injury associated with the use of their products.

14. In that same warning, the FDA expressed concern about the over-the-counter bowel cleansing product, Fleet Phospho-soda, when ingested in higher doses for bowel cleansing in anticipation of a colonoscopy. The FDA’s statement provides:

[I]n light of the risk of acute phosphate nephropathy, over-the-counter laxative OSP product should not be used for bowel cleansing. Consumers should only use OSPs for bowel cleansing pursuant to a prescription from a healthcare professional. FDA intends to amend the labeling conditions for OSP products available in the OTC setting to address this concern with bowel cleansing use and to improve the safe use of OSP’s that are available over-the-counter.

15. In conjunction with the FDA announcement, the C.B. Fleet Company announced an immediate voluntary recall of various over-the-counter bowel cleansing products including Fleet Phospho-soda.

16. Even prior to the FDA's warning of December of 2008, the Defendants had notice based upon published reports that their product, Fleet Phospho-soda, could cause serious injury when administered as prescribed.

17. Significantly, in August of 2005, the American Society of Nephrology published an article entitled "Acute Phosphate Nephropathy following Oral Sodium Phosphate Bowel Purgative: An Underrecognized Cause of Chronic Renal Failure." The article documented 31 cases of nephrocalcinosis among a sampling of 7,349 native renal biopsies processed at Columbia University and found that 21 presented with acute renal failure and had a history of recent colonoscopy preceded by bowel cleansing with oral sodium phosphate solution or Visicol.

18. The study report concludes that oral sodium phosphate products, like Fleet Phospho-soda, are an underrecognized cause of chronic renal failure. Specifically, the article states:

Although renal function may improve, all (100%) patients in this report were left with chronic renal insufficiency and 19% developed ESRD, underscoring the importance of acute phosphate nephropathy as a cause of chronic irreversible renal injury. Our findings strongly suggest the need for further study and possibly revised guidelines to address the use of OSPS in older patients who have a history of hypertension and are receiving ACE-I, ARB, diuretics, or NSAIDs.

19. On or about April 17, 2003, Plaintiff Stanley Jackson underwent a colonoscopy at Endoscopy Center North in Cincinnati, Ohio. In connection with that colonoscopy, Plaintiff Stanley Jackson was instructed to ingest, and did in fact purchase and ingest, Phospho-soda, manufactured and marketed by the Defendants.

20. Shortly thereafter, Plaintiff Stanley Jackson began experiencing signs and symptoms of renal insufficiency, for which he sought medical treatment. By July of 2003, he was diagnosed with acute renal failure.

21. On April 5, 2004, Plaintiff Stanley Jackson underwent a kidney biopsy. Through the biopsy, he was diagnosed with arterial and arteriolo nephrosclerosis and interstitial nephrocalcinosis.

22. In July or August of 2004, Plaintiff Stanley Jackson began hemodialysis. He continues on hemodialysis to this day and expects that the procedure will be necessary through the rest of his life.

23. At all times relevant hereto, the Defendants knew or should have known that there were safer, alternative designs for bowel cleansing products that would prevent or minimize the risk of renal failure in patients like Plaintiff Stanley Jackson.

24. At all times relevant hereto, the Defendants knew or should have known that their product, Phospho-soda, was not reasonably fit, suitable, or safe for its intended purpose and specifically, that it was defective and unsafe for use in patients like Plaintiff Stanley Jackson, and knew or should have known that their product could cause renal failure when ingested pursuant to its label and instructions.

25. The Defendants consistently failed to warn consumers and/or their healthcare providers that severe, even fatal, injuries could result when Phospho-soda was ingested by patients, such as Plaintiff Stanley Jackson, according to the label and instructions.

26. The Defendants repeatedly and consistently failed to advise consumers and/or their healthcare providers of the propensity of Phospho-soda to cause renal insufficiency when ingested as provided in the product label.

27. The Defendants failed to take prompt, reasonable, and effective measures to alert the appropriate members of the health care community and its patients to the serious adverse health risks presented by Fleet Phospho-soda ingestion.

28. As a direct and proximate result of ingesting Fleet Phospho-soda, Plaintiff Stanley Jackson has suffered serious, progressive, permanent, incurable, and potentially fatal injuries.

29. As a direct and proximate result of ingesting Fleet Phospho-soda, Plaintiff Stanley Jackson has incurred medical expenses and other economic harm and has further experienced limited mobility, dramatic life changes, severe and debilitating physical and emotional pain and distress, and other non-economic harm.

30. Prior to April 2003, the Defendants knew or should have known that the ingestion of Phospho-soda could cause kidney damage to patients such as Plaintiff Stanley Jackson and could cause patients to develop chronic renal failure.

31. Therefore, at the time Plaintiff Stanley Jackson ingested Fleet Phospho-soda, the Defendants knew or should have known that the use of Phospho-soda created an increased risk to such consumers of serious personal injury and death.

32. Despite the fact that the Defendants knew or should have known of the serious health risks associated with Fleet Phospho-soda, the Defendants failed to warn Plaintiff Stanley Jackson and/or his healthcare providers of such serious risks.

33. Had Plaintiff Stanley Jackson and/or his healthcare providers known of the risks associated with Fleet Phospho-soda, he would not have ingested Phospho-soda and would not have developed chronic renal failure.

34. As a direct and proximate result of orally ingesting Phospho-soda and subsequently developing renal failure, Plaintiff Stanley Jackson has suffered economic loss and pecuniary harm including, but not limited to, the following:

- a. Lost wages, salaries, or other compensation;
- b. All expenditures for medical care or treatment, rehabilitation services, or other care, treatment, services, products or accommodations, and/or
- c. Other expenditures.

35. As such, Plaintiff Stanley Jackson has suffered economic damages, losses, and expenses, and non-economic damages including, but not limited to conscious pain and suffering, physical injury and bodily impairment, emotional distress, mental anguish, and other intangible loss, and he will continue to suffer such harm and injury into the future.

36. Specifically, Plaintiff Stanley Jackson has suffered permanent and substantial physical deformity and/or the loss of use of a bodily organ system. His injury is permanent in nature, and it permanently prevents him from being able to independently care of himself and perform life-sustaining activities.

37. As a direct and proximate result of Plaintiff Stanley Jackson ingesting Fleet Phospho-soda, Plaintiff Barbara Jackson has suffered economic damages, losses and expenses, and non-economic damages including, but not limited to, pain and

suffering, loss of society, consortium, companionship, care, assistance, attention, protection, advice, guidance, counsel, instruction, training, or education, and mental anguish and emotional distress, and she will continue to suffer such harm and injury into the future.

38. Upon information and belief, the Defendants failed or may have failed to comply with all federal standards and requirements applicable to the sale of the over-the-counter drug Phospho-soda including, but not limited to, violations of various sections and subsections of the United States Code and the Code of Federal Regulations, including but not limited to those contained in 21 C.F.R. § 330, *et seq.*

FIRST CAUSE OF ACTION

STRICT PRODUCTS LIABILITY DEFECTIVE MANUFACTURING O.R.C. § 2307.74

39. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

40. At all relevant times, the Defendants were in the business of manufacturing, designing, formulating, producing, constructing, creating, assembling, rebuilding, selling, distributing, supplying, marketing, and/or placing into the stream of commerce the drug Phospho-soda.

41. The Phospho-soda manufactured, designed, formulated, produced, constructed, created, assembled, rebuilt, sold, distributed, supplied, marketed, and/or placed into the stream of commerce by the Defendants was defective in its manufacture and construction when it left the hands of the Defendants in that it deviated in a material

way from the design specifications, formula, or performance standards of the manufacturer or from otherwise identical units.

42. As a direct and proximate result of Plaintiff Stanley Jackson ingesting Phospho-soda as manufactured, designed, formulated, produced, constructed, created, assembled, rebuilt, sold, distributed, supplied, marketed, and/or placed into the stream of commerce by the Defendants, as well as the Defendants' failure to comply with all federal standards and requirements, Plaintiff Stanley Jackson suffered economic damages, losses, and expenses, and non-economic damages including, but not limited to conscious pain and suffering, physical injury and bodily impairment, and emotional distress, and he will continue to suffer such harm and injury into the future.

43. The Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for the safety of persons who may be harmed by Phospho-soda, indicate that Defendants acted maliciously with aggravated or egregious fraud, and/or indicate that the Defendants intentionally disregarded Plaintiff's rights, thus warranting the imposition of punitive damages.

SECOND CAUSE OF ACTION

**STRICT PRODUCTS LIABILITY
DEFECTIVE DESIGN OR FORMULATION
O.R.C. § 2307.75**

44. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

45. At all relevant times, the Defendants were in the business of manufacturing, designing, formulating, producing, constructing, creating, assembling,

rebuilding, selling, distributing, supplying, marketing, and/or placing into the stream of commerce the drug Phospho-soda.

46. The Phospho-soda manufactured, designed, formulated, produced, constructed, created, assembled, rebuilt, sold, distributed, supplied, marketed, and/or placed into the stream of commerce by the Defendants was defective in design or formulation in that, when it left the hands of the Defendants, the foreseeable risks of the product exceeded the benefits associated with its design or formulation.

47. The foreseeable risks associated with the design or formulation of Phospho-soda include, but are not limited to, the following:

- a. The nature and magnitude of the risk of kidney failure associated with the design and formulation of Phospho-soda outweighs the benefits associated with the reasonably foreseeable uses for the product;
- b. The product users, including Plaintiff Stanley Jackson, are unlikely to be aware of the risk of kidney failure associated with the design and formulation of Phospho-soda for reasons including, but not limited to, their lack of general knowledge about such products and the Defendants' failure to provide adequate warnings;
- c. The likelihood that the design or formulation of Phospho-soda can cause harm to product users like Plaintiff Stanley Jackson outweighs the benefits associated with the reasonably foreseeable uses for the product;
- d. The design and formulation of Phospho-soda failed to conform to applicable public and private product standards in effect at the time

the product left the Defendants' control, including but not limited to the provisions of the United States Code and the Code of Federal Regulations applicable to over-the-counter drugs; and/or

- e. The design and formulation of Phospho-soda is more dangerous than a reasonably prudent consumer would expect when used in its intended or reasonably foreseeable manner.

48. The benefits associated with the design and/or formulation of Phospho-soda do not outweigh the risks of severe renal impairment to product users like Plaintiff Stanley Jackson. The intended or actual utility of the product is outweighed by the risks, and alternative designs and/or formulations were technologically and economically feasible at the time the Defendants manufactured and marketed Phospho-soda. Such alternative designs would have been safer for product users including Plaintiff Stanley Jackson.

49. As a direct and proximate result of Plaintiff Stanley Jackson ingesting Phospho-soda as manufactured, designed, formulated, produced, constructed, created, assembled, rebuilt, sold, distributed, supplied, marketed, and/or placed into the stream of commerce by the Defendants, as well as the Defendants' failure to comply with all federal standards and requirements, Plaintiff Stanley Jackson suffered economic damages, losses, and expenses, and non-economic damages including, but not limited to conscious pain and suffering, physical injury and bodily impairment, and emotional distress, and he will continue to suffer such harm and injury into the future.

50. The Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for the safety of persons who may be harmed by

Phospho-soda, indicate that Defendants acted maliciously with aggravated or egregious fraud, and/or indicate that the Defendants intentionally disregarded Plaintiff's rights, thus warranting the imposition of punitive damages.

THIRD CAUSE OF ACTION

**STRICT PRODUCTS LIABILITY
DEFECT DUE TO INADEQUATE WARNING
O.R.C. § 2307.76**

51. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

52. At all relevant times, the Defendants were in the business of manufacturing, designing, formulating, producing, constructing, creating, assembling, rebuilding, selling, distributing, supplying, marketing, and/or placing into the stream of commerce the drug Phospho-soda.

53. The Phospho-soda manufactured, designed, formulated, produced, constructed, created, assembled, rebuilt, sold, distributed, supplied, marketed, and/or placed into the stream of commerce by the Defendants was defective due to inadequate warning or instruction because, at the time the product left the Defendants' hands, the Defendants knew or, in the exercise of reasonable care, should have known that their product could cause severe renal impairment when ingested by product users like Plaintiff Stanley Jackson, and the Defendants failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning the risk of severe renal impairment.

54. As a direct and proximate result of Plaintiff Stanley Jackson ingesting Phospho-soda as manufactured, designed, formulated, produced, constructed, created,

assembled, rebuilt, sold, distributed, supplied, marketed, and/or placed into the stream of commerce by the Defendants, as well as the Defendants' failure to comply with all applicable federal standards and requirements, Plaintiff Stanley Jackson suffered economic damages, losses, and expenses, and non-economic damages including, but not limited to conscious pain and suffering, physical injury and bodily impairment, and emotional distress, and he will continue to suffer such harm and injury into the future.

55. The Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for the safety of persons who may be harmed by Phospho-soda, indicate that Defendants acted maliciously with aggravated or egregious fraud, and/or indicate that the Defendants intentionally disregarded Plaintiff's rights, thus warranting the imposition of punitive damages.

FOURTH CAUSE OF ACTION

STRICT PRODUCTS LIABILITY DEFECT DUE TO INADEQUATE POST-MARKETING WARNING O.R.C. § 2307.76

56. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

57. At all relevant times, the Defendants were in the business of manufacturing, designing, formulating, producing, constructing, creating, assembling, rebuilding, selling, distributing, supplying, marketing, and/or placing into the stream of commerce the drug Phospho-soda.

58. The Phospho-soda manufactured, designed, formulated, produced, constructed, created, assembled, rebuilt, sold, distributed, supplied, marketed, and/or

placed into the stream of commerce by the Defendants was defective due to inadequate post-marketing warning or instruction because after the product left the control of the Defendants, the Defendants knew or, in the exercise of reasonable care, should have known that their product could cause severe renal impairment when ingested by product users like Plaintiff Stanley Jackson, and the Defendants failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning the risk of severe renal impairment.

59. As a direct and proximate result of Plaintiff Stanley Jackson ingesting Phospho-soda as manufactured, designed, formulated, produced, constructed, created, assembled, rebuilt, sold, distributed, supplied, marketed, and/or placed into the stream of commerce by the Defendants, as well as the Defendants' failure to comply with all applicable federal standards and requirements, Plaintiff Stanley Jackson suffered economic damages, losses, and expenses, and non-economic damages including, but not limited to conscious pain and suffering, physical injury and bodily impairment, and emotional distress, and he will continue to suffer such harm and injury into the future.

60. The Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for the safety of persons who may be harmed by Phospho-soda, indicate that Defendants acted maliciously with aggravated or egregious fraud, and/or indicate that the Defendants intentionally disregarded Plaintiff's rights, thus warranting the imposition of punitive damages.

FIFTH CAUSE OF ACTION

**STRICT PRODUCTS LIABILITY
DEFECT DUE TO NONCONFORMANCE WITH REPRESENTATIONS
O.R.C. § 2307.77**

61. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

62. At all relevant times, the Defendants were in the business of manufacturing, designing, formulating, producing, constructing, creating, assembling, rebuilding, selling, distributing, supplying, marketing, and/or placing into the stream of commerce the drug Phospho-soda.

63. The Defendants made representations regarding the character or quality of Phospho-soda.

64. The Phospho-soda manufactured, designed, formulated, produced, constructed, created, assembled, rebuilt, sold, distributed, supplied, marketed, and/or placed into the stream of commerce by the Defendants was defective in that, when it left the hands of the Defendants, it did not conform to representations made concerning the product.

65. Plaintiff Stanley Jackson and/or his health care providers justifiably relied upon the Defendants' representations regarding Phospho-soda at the time it was prescribed and ingested by Plaintiff Stanley Jackson.

66. As a direct and proximate result of Plaintiff Stanley Jackson's ingestion of Phospho-soda and the reliance on the Defendants' representations regarding the character and quality of Phospho-soda, as well as the Defendants' failure to comply with all federal standards and requirements, Plaintiff Stanley Jackson suffered economic

damages, losses, and expenses, and non-economic damages including, but not limited to conscious pain and suffering, physical injury and bodily impairment, and emotional distress, and he will continue to suffer such harm and injury into the future.

67. The Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for the safety of persons who may be harmed by Phospho-soda, indicate that Defendants acted maliciously with aggravated or egregious fraud, and/or indicate that the Defendants intentionally disregarded Plaintiff's rights, thus warranting the imposition of punitive damages.

SIXTH CAUSE OF ACTION

NEGLIGENCE

68. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

69. The Defendants had a duty to exercise reasonable care in the manufacturing, designing, formulating, producing, constructing, creating, assembling, rebuilding, selling, distributing, supplying, marketing, and/or placing into the stream of commerce the drug Fleet Phospho-soda, including a duty to ensure that its product did not pose a significantly increased risk of bodily harm and adverse events.

70. The Defendants failed to exercise ordinary care in manufacturing, designing, formulating, producing, constructing, creating, assembling, rebuilding, selling, distributing, supplying, marketing, and/or placing into the stream of commerce, the drug Fleet Phospho-soda in that the Defendants knew or should have known that the product

caused such significant bodily harm or death and was not safe for ingestion by consumers.

71. The Defendants also failed to exercise ordinary care in the labeling of Phospho-soda and failed to issue to consumers and/or their health care providers adequate warnings of the risk of serious bodily injury or death due to the use of the Phospho-soda.

72. Despite the fact that the Defendants knew or should have known that Phospho-soda posed a serious risk of bodily harm to consumers, the Defendants continued to manufacture and market Phospho-soda for ingestion as a bowel cleanser to patients such as Plaintiff Stanley Jackson.

73. The Defendants knew or should have known that consumers such as Plaintiff Stanley Jackson would foreseeably suffer injury as a result of the Defendants' failure to exercise ordinary care as described above.

74. As a direct and proximate result of the Defendants' negligence, as well as the Defendants' failure to comply with all applicable federal standards and requirements, Plaintiff Stanley Jackson suffered economic damages, losses, and expenses, and non-economic damages including, but not limited to conscious pain and suffering, physical injury and bodily impairment, and emotional distress, and he will continue to suffer such harm and injury into the future.

75. The Defendants' conduct as described above, including but not limited to its failure to adequately test Phospho-soda, to provide adequate warnings, and its continued manufacture, sale, and marketing of the product when it knew or should have known of the serious health risks created, demonstrate a flagrant disregard for the

safety of persons who may be harmed by Phospho-soda, thus warranting the imposition of punitive damages.

SEVENTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

76. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

77. The Defendants expressly warranted that Phospho-soda was a safe and effective bowel cleanser for use by patients such as Plaintiff Stanley Jackson.

78. The Phospho-soda manufactured and sold by the Defendants did not conform to these express representations because it caused serious injury to consumers when ingested in suggested dosages.

79. As a direct and proximate result of the Defendants' breach of warranty, as well as the Defendants' failure to comply with all applicable federal standards and requirements, Plaintiff Stanley Jackson suffered economic damages, losses, and expenses, and non-economic damages including, but not limited to conscious pain and suffering, physical injury and bodily impairment, and emotional distress, and he will continue to suffer such harm and injury into the future.

EIGHTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY

80. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

81. At the time the Defendants manufactured, marketed, sold, and distributed Phospho-soda, the Defendants knew of the use for which Phospho-soda was intended and impliedly warranted Phospho-soda to be of merchantable quality and safe for such use.

82. Plaintiff Stanley Jackson and his health care providers reasonably relied upon the skill and judgment of the Defendants as to whether Phospho-soda was of merchantable quality and safe for its intended use and upon the Defendants' implied warranty as to such matters.

83. Contrary to the implied warranty, Phospho-soda was not of merchantable quality or safe for its intended use because it was unreasonably dangerous as described herein.

84. As a direct and proximate result of the Defendants' breach of warranty, as well as the Defendants' failure to comply with all applicable federal standards and requirements, Plaintiff Stanley Jackson suffered economic damages, losses, and expenses, and non-economic damages including, but not limited to conscious pain and suffering, physical injury and bodily impairment, and emotional distress, and he will continue to suffer such harm and injury into the future.

NINTH CAUSE OF ACTION

MISREPRESENTATION

85. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

86. At all relevant times, the Defendants were in the business of manufacturing, designing, formulating, producing, constructing, creating, assembling, rebuilding, selling, distributing, supplying, marketing, and/or placing into the stream of commerce the drug Phospho-soda.

87. The Defendants made material misrepresentations regarding the safety and effectiveness of their product, Phospho-soda.

88. In the alternative, the Defendants concealed material information about the safety and effectiveness of Phospho-soda from consumers, including Plaintiff Stanley Jackson, when it had a duty to disclose such information.

89. The Defendants had actual knowledge based upon studies, published reports and clinical experience that Phospho-soda created an unreasonable risk of serious bodily injury and death to consumers, or should have known such information.

90. The Defendants intentionally or negligently omitted this information in its product labeling, promotions and marketing and instead labeled, promoted and marketed its product as safe in order to avoid losses and sustain profits in its sales to consumers.

91. Plaintiff Stanley Jackson reasonably relied to his detriment upon Defendants' actions and omissions in its labeling, marketing, and promotions concerning the serious risks posed by the product. Plaintiff Stanley Jackson reasonably relied upon Defendants' representations to him and/or his health care providers that Phospho-soda was safe for human consumption and/or use and that the Defendants' labeling, marketing and promotions fully described all known risks of the product.

92. As a direct and proximate result of the Defendants' negligent actions and omissions, as well as the Defendants' failure to comply with all applicable federal standards and requirements, Plaintiff Stanley Jackson ingested Phospho-soda and Plaintiff Stanley Jackson suffered economic damages, losses, and expenses, and non-economic damages including, but not limited to conscious pain and suffering, physical injury and bodily impairment, and emotional distress, and he will continue to suffer such harm and injury into the future.

93. The Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for the safety of persons who may be harmed by Phospho-soda, indicate that Defendants acted maliciously with aggravated or egregious fraud, and/or indicate that the Defendants intentionally disregarded Plaintiff's rights, thus warranting the imposition of punitive damages.

TENTH CAUSE OF ACTION

LOSS OF CONSORTIUM CLAIM ON BEHALF OF PLAINTIFF BARBARA JACKSON

94. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

95. At all relevant times, Plaintiffs Stanley and Barbara Jackson have been married.

96. As a direct and proximate result of the Defendants' actions as described herein, including but not limited to their failure to comply with federal standards, Plaintiff Barbara Jackson has suffered the loss of her husband's services, companionship, society, and consortium, emotional distress and mental anguish, and she will continue to suffer such loss and damages in the foreseeable future.

WHEREFORE, Plaintiffs pray for relief as follows:

1. Compensatory and punitive damages in excess of the jurisdictional amount, including, but not limited to non-economic damages in excess of \$350,000.00;
2. Medical expenses and other economic damages in an amount to be determined at trial of this action;
3. Pre-judgment and post-judgment interest;
4. Attorneys' fees, expenses, and costs of this action;
5. Punitive damages in excess of twice the compensatory damages award;
6. Such further relief as this Court deems necessary, just, and proper.

Respectfully submitted,

/s/ Janet G. Abaray
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JURY DEMAND

Plaintiffs hereby demand a trial by jury.

/s/ Janet G. Abaray
Janet G. Abaray